UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,660	08/27/2002	Janet Mary Hock	X-13288	9334

25885 7590 09/09/2004

ELI LILLY AND COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
1654	10

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,660	HOCK ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *47-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The previous Election/Restriction requirement is withdrawn. The new Election/Restriction requirement is now made in its place. Claims 47-62 are pending. Claims 47-62 are subject to an Election/Restriction requirement.

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 47-50, drawn to drawn to a method of monitoring the effect of PTH to a subject by determining an enzyme level indicative of an osteoblastic process of bone formation.

Group II, claim(s) 51-53, drawn to drawn to a method of monitoring the effect of PTH to a subject by determining a product of collagen biosynthesis.

Group III, claim(s) 37, 54-55, and 56, drawn to drawn to a method of monitoring the effect of PTH to a subject by determining a product of collagen degradation.

Group IV, claim(s) 47 and 56, drawn to a method of monitoring the effect of PTH to a subject by determining a combination of a level of an enzyme indicative of an osteoblastic process of bone formation, a product of collagen biosynthesis.

Group V, claim(s) 57, drawn to a kit for monitoring the effect of administration of a parathyroid hormone to a subject, comprising a container, a reagent for determining a level of a product of collagen biosynthesis and instructions for monitoring.

Group VII, claim(s) 57, drawn to drawn to a kit for monitoring the effect of administration of a parathyroid hormone to a subject, comprising a container, a reagent for determining a level of a product of collagen degredation and instructions for monitoring.

Group VIII, claim(s) 58, drawn to drawn to a method for using change in biochemical marker of bone formation from collagen biosynthesis for predicting subsequent change in spine bone mineral density resulting from repetitive administration of a PTH.

Group IX, claim(s) 59-61, drawn to a method for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a male human subject at risk of or having osteoporosis.

Group X, claim(s) 62, drawn to an article of manufacture consisting of PTH sequence 1-34 and ministered to a subject.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: A method for monitoring an effect of administration of a parathyroid hormone to a subject by determining a level of changes in biochemical markers of bone formation, i.e. total serum alkaline phosphates (SAP, bone-specific alkaline phosphates (BSAP) and osteocalcin. See Hodsman, et al. A Randomized Controlled Trail to compare the Efficacy of Cyclical parathyroid Hormone Versus Cyclical Parathyroid Hormone and Sequential Calcitonin to Improve Bone Mass in Post Menopausal Women with Osteoporosis, Journal of Clinical Endocrinology and metabolism, Vol. 82, No. 2, 1997, pp. 620-628 (provided by Applicant). Moreover, administering parathyroid hormone 1-34 to reduce the risk of vertebral and non-bertebral bone fracture in a human is known. See Slovik, et al. Restoration of Spinal Bone in Osteoporotic men by Treatment with Human Parathyroid Hormone (1-34) and 1,25-Dihydroxyvitam D., journal of Bone and Mineral Research, Vol. 1, No. 4, 1986, pp. 377-381 (provided by Applicant).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL MELLER
PRIMARY EXAMINER

Jennifer Ione Harle
August 20, 2004